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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,190	04/10/2001	Katsuya Matsuda	MATSUDA 13	4190

1444 7590 05/20/2005

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,190	MATSUDA ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31,32,34-40,42-49 and 53-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,32,34-40,42-49 and 53-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Continued Examination filed on 4/15/05 and the Declaration under CFR 1.132 filed 3/10/05 is acknowledged. Claims **31-32, 34-40, 42-49, and 53-59** are pending in this application. Claims 1-30, 33, 41, and 50-52 stand cancelled.

Response to Amendment

The Rule 132 Declaration under 37 CFR 1.132 filed 3/10/05 is insufficient to overcome the rejection of claims based upon Holmes-Farley et al (6,423,754) in view of Sato et al (5,202,335) as set forth in the last Office action for the following reasons:

Firstly, it is noted that the applicant utilizes a specific amount of the instant phosphate-binding polymer, microcrystalline cellulose, and L-HPC to provide "increased hardness" and decrease stickiness. However, the instant independent claims do not recite these weight percentages that provide the unexpected properties. Therefore, the claims are not commensurate in scope with the unexpected results. In re Chupp, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987).

Secondly, it is noted that applicant is claiming a tablet hardness of 6 KP or more, however the instant declaration demonstrates that the polymer itself yields a tablet hardness of 6.2. Therefore, the hardness *as claimed* is not unexpected.

Lastly, it is noted that the composition with crystalline cellulose and the polymer provides a hardness of 8.6 and is not sticky. However, the examiner points out that Holmes-Farley teaches the use of microcrystalline cellulose as a suitable carrier. Holmes-Farley incorporates the disclosure of US 5,496,545 and 5,487,888. US '545 on column 17, lines 40-46 teaches the use of microcrystalline cellulose as a suitable carrier. It should be noted that when a

reference is incorporated by reference, the information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. See MPEP 2163.07(b). Therefore, Holmes-Farley clearly suggests the use of instant microcrystalline cellulose and applicant has merely found the property the suggested carrier yields. Moreover, the use of microcrystalline cellulose and l-HPC respectively are known to increase tablet hardness and thus the prior art actually teaches applicant's "unexpected result" when utilizing the respective additive. For instance, US 5,939,099 states that low-substituted hydroxypropylcellulose is "employed as a disintegrant for accelerating the disintegration of tablets. L-HPC can also be employed as a binder for tablets for **increasing tablet hardness**." See column 1, lines 30-37. US 4,347,235 discloses adding microcrystalline cellulose "which functions to **increase tablet hardness**". US 3,146,168 discloses that microcrystalline cellulose has superior compressibility, cohesive strength, and is less tacky and sticky. See column 5, lines 6-10 and 35-74.

Response to Arguments

Applicant's arguments filed 4/15/05 have been fully considered but they are not persuasive.

Applicant argues that Holmes-Farley does not suggest the use of the instant phosphate binding polymers in tablet formulations. Applicant argues that US '754 does not suggest having the instant physical properties. Applicant asserts that there is no motivation to utilize the prior art's phosphate-binding polymer to formulate a tablet since the prior art only teaches capsules.

The examiner points out that although Holmes-Farley's exemplifies capsules, "disclosed examples and preferred embodiments do not constitute a teaching away from a broader

disclosure or nonpreferred embodiments." In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). In instant case, Holmes-Farley not only suggest formulating the polymers in a tablet formulation in column 3, line 53, the prior art suggest the use of microcrystalline cellulose as a suitable carrier.

Applicant argues that the instantly amended claims are direct to a tablet hardness not possessed by the prior art. Applicant argues that the use of the additives increasing tablet hardness. Applicant argues that the specific selection of additives allows one to increase the hardness of the tablet and reduce the size of the tablet to ease oral administration. Applicant argues that the instant polymer swell in the oral cavity making it difficult to swallow the tablet; however the instant additives prevent swelling in the cavity and the tablet does not adhere to the mucosa in the oral cavity.

Firstly, it should be noted as discussed above, that applicant's claiming a hardness of 6 KP and the instant declaration demonstrates that the instant polymers provide a hardness of 6.2. Therefore, the applicant's argument that the instant polymers do not possess the instant hardness as claimed, is perplexing. Secondly, the examiner points out that the applicant is not claiming the tablet size and thus is relying on features that are not claimed. Lastly with regard to applicant's assertion that the instant additives prevent swelling in the oral cavity, etc, the examiner points out that applicant's declaration does not demonstrated this property. Thus, applicant arguments are not substantiated with evidence.

Claim Objections

Claims 42-49 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel

the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 42-49 are directed to a tablet but depend from a process claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-32, 34-40, 42-49, and 53-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims 31 and 39 recite "at least one of crystalline cellulose and low substituted hydroxypropyl cellulose" which is indefinite. It is unclear if the claims require either crystalline cellulose **or** L-HPC or the claim requires at least one type of crystalline cellulose **and** L-HPC. The examiner suggest restructuring the claims to recite "at least one of crystalline cellulose or low-substituted cellulose" if the applicant intends the tablet to have either crystalline cellulose or L-HPC. For examination purposes, prior art will be applied using the first interpretation.

Claim 31 is directed to "A tablet having a hardness of 6PK", which is indefinite since it is unclear what the unit PK is. Further clarification is requested.

Claim 55 recites "wherein said table has a weight loss of 1% or less" which is indefinite since it is unclear what the intended limitation. It appears "tablet" should be "tablet".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 31-32, 36, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754).

Holmes-Farley et al disclose the method of preparing cross-linked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia. See abstract and column 3, lines 35-50. The polymers are prepared by combining polyallylamine hydrochloride, acetonitrile, water, and epichlorohydrin, yielding particles in a solution. The solid particles are then dried and passed thorough a 50-mesh screen (approximately 300 microns). See examples on column 6, lines 15-45. Suitable forms for administration are tablets, capsules, or powders. The polymer may be administered alone or in combination with a carrier such as magnesium carbonate, lactose, etc and can be coated to protect the composition from disintegration. See column 3, lines 35-60. Further, the disclosure of US 5,496,545 and 5,487,888 are incorporated

by reference. US '545 on column 17, lines 40-46 teaches the use of microcrystalline cellulose as a suitable carrier.

It should be noted that although the prior art does not teach the instant specific gravity and properties, it is the examiner's position that these are inherent in Holmes-Farley since applicant discloses the instant phosphate-binding polymers have the instant specific gravity due to the specific preparation utilizing a solvent mixture of water and acetonitrile and crosslinking polyallyamine with epichlorohydrin, which is the same solvent mixture utilized by the prior art to prepare the phosphate-binding polymer particles. Further, the submitted declaration of 3/10/05 demonstrates that the instant polymers by themselves have a hardness of 6.2 KP.

Holmes-Farley et al does not exemplify the tablet formulation.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Holmes-Farley et al and utilize a tablet formulation containing the phosphate-binding polymer. One would be motivated to do so with the expectation of similar results since the prior art clearly teaches that the tablets are suitable form for administering the instant polymers. Thus, one would be motivated to utilize the dosage form of choice depending on the desired type of administration. Secondly, Holmes-Farley suggests the use of microcrystalline cellulose as a suitable carrier; therefore a skilled artisan would have been motivated to utilize microcrystalline cellulose with a reasonable expectation of success.

Claims 34-35, 39-40, 42-46, 49 and 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Chen et al (5,225,204).

Holmes-Farley et al disclose the method of preparing cross-linked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia. See abstract and

column 3, lines 35-50. The polymers are prepared by combining polyallylamine hydrochloride, acetonitrile, water, and epichlorohydrin, yielding particles in a solution. The solid particles are then dried and passed thorough a 50-mesh screen (approximately 300 microns). See examples on column 6, lines 15-45. Suitable forms for administration are tablets, capsules, or powders. The polymer may be administered alone or in combination with a carrier such as magnesium carbonate, lactose, etc and can be coated to protect the composition from disintegration. See column 3, lines 35-60. Further, the disclosure of US 5,496,545 and 5,487,888 are incorporated by reference. US '545 on column 17, lines 40-46 teaches the use of microcrystalline cellulose as a suitable carrier.

It should be noted that although the prior art does not teach the instant specific gravity and properties, it is the examiner's position that these are inherent in Holmes-Farley since applicant discloses the instant phosphate-binding polymers have the instant specific gravity due to the specific preparation utilizing a solvent mixture of water and acetonitrile and crosslinking polyallyamine with epichlorohydrin, which is the same solvent mixture utilized by the prior art to prepare the phosphate-binding polymer particles. Further, the submitted declaration of 3/10/05 demonstrates that the instant polymers by themselves have a hardness of 6.2 KP.

Holmes-Farley et al does not expressly teach the compression of the granules into a tablet form or the use of l-HPC.

Chen et al teach a stable dosage form of levothyroxine. Chen teaches conventional tabletting aids include HPC, HEC, L-HPC, microcrystalline cellulose, and lubricants,. Chen teaches the process of making a tablet wherein the active agent, 120g microcrystalline cellulose,

10g L-HPC, and a magnesium stearate lubricant are combined and compressed into a tablet form with a hardness of 14-19kp.

Further, it would have been ordinary skill in the art at the time the invention was made to look to the guidance provided Chen and formulate Holmes-Farley's phosphate-binding polymers into a tablet. One would have been motivated to look to Chen with a reasonable expectation of success since Chen teaches the process of making a tablet with the instant conventional excipient, microcrystalline cellulose and Holmes-Farley not only suggests the use of tablet forms but suggests the use of microcrystalline cellulose as a carrier.

With regard to the limitations of claims 54-59, it is the examiner's position that since the prior art teaches the same phosphate binder and the same excipient (microcrystalline cellulose) the hardness would be the same absent evidence to the contrary. Moreover, although Chen utilizes a different active agent and not the instant active agent (phosphate-binding polymers), Chen teaches a tablet utilizing the instant excipients, MCC and l-HPC, has a hardness of 14-19 KP. Therefore, it is the examiner's position that it is well known in the art that the instant excipients increase tablet hardness.

Claims 37 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Chen et al (5,225,204) in further view of Nakajima (3926817).

The teachings of Holmes-Farley and Chen have been discussed above.

The references do not teach the instant lubricant: hardened oil.

Nakajima teaches stearic acid, magnesium stearate, and hydrogenated castor oil have been widely employed in various pharmaceutical preparations. See column 2, lines 50-55.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and utilize the instant hydrogenated oil in place of Chen's magnesium stearate. One would have been motivated to do so since Nakajima teaches the instant lubricant and the prior art's magnesium stearate are both utilized as glidants in pharmaceutical compositions. Therefore, it is prima facie obvious to substitute one functional equivalent for another functionally equivalent agent with the expectation of success.

Claims 31-32, 34, 36, 39-40, 42, 49, and 53-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Yaginuma et al (5,574,150) or Battista (3,146,168).

Holmes-Farley et al disclose the method of preparing cross-linked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia. See abstract and column 3, lines 35-50. The polymers are prepared by combining polyallylamine hydrochloride, acetonitrile, water, and epichlorohydrin, yielding particles in a solution. The solid particles are then dried and passed thorough a 50-mesh screen (approximately 300 microns). See examples on column 6, lines 15-45. Suitable forms for administration are tablets, capsules, or powders. The polymer may be administered alone or in combination with a carrier such as magnesium carbonate, lactose, etc and can be coated to protect the composition from disintegration. See column 3, lines 35-60. Further, the disclosure of US 5,496,545 and 5,487,888 are incorporated by reference. US '545 on column 17, lines 40-46 teaches the use of microcrystalline cellulose as a suitable carrier.

It should be noted that although the prior art does not teach the instant specific gravity and properties, it is the examiner's position that these are inherent in Holmes-Farley since

applicant discloses the instant phosphate-binding polymers have the instant specific gravity due to the specific preparation utilizing a solvent mixture of water and acetonitrile and crosslinking polyallyamine with epichlorohydrin, which is the same solvent mixture utilized by the prior art to prepare the phosphate-binding polymer particles. Further, the submitted declaration of 3/10/05 demonstrates that the instant polymers by themselves have a hardness of 6.2 KP.

Holmes-Farley et al does not exemplify the tablet formulation. Although, Holmes-Farley suggests the use of microcrystalline cellulose, the excipient is not exemplified.

Yaginuma et al disclose an improved microcrystalline cellulose with high compactability. Yaginuma discloses the *conventional and wide use* of microcrystalline cellulose in the art since it exhibits high safety, a relatively high compactability and a relatively excellent rate of disintegration. Further, Yaginuma teaches the prior art disclosing the use of microcrystalline cellulose to increase strength of tablets. See column 1, lines 16-40. However, Yaginuma teaches the prior art's microcrystalline cellulose have disadvantages in that when the compactability is high, the rate of disintegration is lowered and when the rate of disintegration is high, the compactability is low. However, Yaginuma teaches an improved microcrystalline cellulose with both high compactability and disintegration. See column 3, lines 30-37. Further, the reference teaches the inventive microcrystalline cellulose may be used in a limited amount to make a small tablet and yet provide the same properties. See column 15, lines 25-32. Yaginuma teaches tablets require at least 4 kgf (4kp) breaking strength and the inventive microcrystalline cellulose provides a strength of 10 kgf (10kp) or mere. See column 15, line 40 to column 14, lines 15.The examples teach combining inventive microcrystalline cellulose (19%) with an active, and lactose and compressing the mixture.

Battista teaches manufacturing pharmaceutical composition containing crystalline cellulose aggregates. Battista teaches in comparison with prior art excipients such as starch and lactose, the crystalline cellulose provides superior compressibility during direct compression and cohesive power. Further, Battista teaches crystalline cellulose has excellent flow ability and is less tacky and sticky than starch. See column 15. example 16 utilizes 25% of the cellulose powder.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Holmes-Farley and Yaginuma or Battista and select instant microcrystalline cellulose. One would have been motivated to do so since Yaginuma teaches the state of the art wherein it is known and conventional to use microcrystalline cellulose to increase the strength of a tablet. Moreover, Yaginuma teaches an improved microcrystalline cellulose that not only improves strength to yield a tablet having a hardness of 10 KP but also good disintegration. Battista also teaches crystalline cellulose provide increased compactability (hardness) to pharmaceutical tablets. Therefore, if a skilled artisan desired to increase the strength of tablet, it would have been prima facie to utilize microcrystalline cellulose as the excipient of choice.

With regard to the limitations of claims 54-59, it is the examiner's position that since the prior art teaches the same phosphate binder and the same excipient (microcrystalline cellulose) the hardness would be the same absent evidence to the contrary.

Claims 35, 37-38, and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Yaginuma et al (5,574,150) or Battista (3,146,168) in further view of Sato et al (5,202,335).

Holmes Farley, Yaginuma, and Battista have been discussed above.

The references do not teach the additional use of instant l-HPC or a lubricant. Further, although Holmes-Farley teaches using a coating, the reference does not specify the type of coating.

Sato et al teach succinic compounds for oral administration. Sato teaches that in molding pharmaceutical compositions into tablet formulations, many conventional carriers known in the art may be used. These carriers include lactose, sucrose, microcrystalline cellulose, etc. Sato also teaches the use of conventional disintegrators such as low-substituted HPC and the use of glidants. The tablets may be coated with a sugar coating, gelatin coating, enteric coating, and film coating, depending on the desired effect. See column 8, lines 54-68. Sato teaches various suitable excipients for the composition that are known in the art. See column 9, lines 1-16.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Holmes-Farley et al, Yaginuma, and Battista and Sato et al and further add L-HPC. One would have been motivated to do so since Sato teaches L-HPC is a conventional disintegrant in the tabletting art. Thus, a skilled artisan would have been motivated to utilize instant l-HPC as a disintegrant in the composition to manipulate the disintegration of the tablet. Lastly, skilled artisan would be motivated to coat the tablet depending on the desired effect of the composition, i.e. a sugar coat for a palatable tablet or a film coat for a smooth, glossy appearance.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-32, and 34-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,383,518 and 6,696,087. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to similar subject matter.

The instant application is directed to a tablet having a hardness of 6KP and comprising phosphate-binding polymers with particle size of no larger than 500 microns and at least one of crystalline cellulose and l-HPC. The particles have a moisture content of 1-14%. Claim 37 is directed to the use of a hardened oil. Claim 38 is to the tablet having a water-soluble coating.

US '518 is directed to a tablet comprising a phosphate binding polymer having a specific formula and having a particle size of 500 microns or less, and crystalline cellulose and/or l-HPC. Claim 2 is directed to a tablet that comprises phosphate-binding polymers with a moisture content of 1-14% and crystalline cellulose and/or l-HPC. Dependent claims are directed to the use of a hardened oil. Dependent claims are directed to a tablet having water-soluble coating.

US '087 is directed to a tablet with a hardness of 6KP or more comprising phosphate-binding polymers having a specific formula and crystalline cellulose and/or l-HPC. Dependent claims are directed to the use of a hardened oil. Dependent claims are directed to a tablet having water-soluble coating.

The instant application, which does not specify the formula of the phosphate-binding polymer, is directed to the broader scope of US patents '518 and '087. Thus, the instant application fully encompasses the subject matter of the patented claims.

Conclusion

None of the claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi

Examiner
Art Unit 1616

SSG

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